



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Office of the Secretary**

#### **Notice of Amendment to the January 1, 2016 Republished Declaration under the Public Readiness and Emergency Preparedness Act**

**ACTION:** Notice of amendment.

#### **SUMMARY:**

The Secretary is amending the declaration first issued on October 10, 2008, and amended and republished effective January 1, 2016 for Smallpox countermeasures and countermeasures against other orthopoxviruses pursuant to section 319F-3 of the Public Health Service Act to emphasize that the declaration applies to monkeypox virus, to expand the categories of providers authorized to administer vaccines and therapeutics against smallpox (variola virus), monkeypox virus, and other orthopoxviruses in a declared emergency, and to extend the duration of the declaration.

#### **DATES:**

This amendment of the January 1, 2016 republished declaration is effective September 28, 2022.

#### **FOR FURTHER INFORMATION CONTACT:**

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#### **SUPPLEMENTARY INFORMATION:**

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the administration or use of medical countermeasures (Covered Countermeasures), except for claims that meet the PREP Act's definition of willful

misconduct. The Secretary may, through publication in the Federal Register, amend any portion of a declaration. Using this authority, the Secretary issued a declaration for smallpox countermeasures against variola virus or other orthopoxviruses on October 10, 2008, amended the declaration effective January 1, 2016, and is further amending this declaration.

The PREP Act was enacted on December 30, 2005, as Public Law 109-148, Division C, Section 2. It amended the Public Health Service (PHS) Act, adding section 319F-3, which addresses liability immunity, and section 319F-4, which creates a compensation program. These sections are codified in the U.S. Code as 42 U.S.C. 247d-6d and 42 U.S.C. 247d-6e, respectively. Section 319F-3 of the PHS Act has been amended by the Pandemic and All-Hazards Preparedness Reauthorization Act, Public Law 113-5, enacted on March 13, 2013, and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116-136, enacted on March 27, 2020, to expand Covered Countermeasures under the PREP Act.

On August 4, 2022, the Secretary determined pursuant to section 319 of the PHS Act, 42 USC 247d, that a public health emergency exists nationwide as a result of the consequences of an outbreak of monkeypox cases across multiple states. Monkeypox is a rare disease caused by infection with the monkeypox virus. Monkeypox virus is an orthopoxvirus, part of the same family of viruses as variola virus, the virus that causes smallpox.

The Secretary is now amending this PREP Act declaration to: amend the title of the declaration to emphasize that it covers monkeypox virus; add to Section I his determination that the 2022 outbreak of monkeypox cases in the United States caused by the monkeypox virus presents a public health emergency for the purposes of the PREP Act; make more explicit in Section I that the declaration applies to public health threats arising from smallpox (variola virus), monkeypox virus, and other orthopoxviruses; authorize in section V additional qualified persons to administer vaccines and therapeutics to address the current public health emergency caused by the 2022 outbreak of monkeypox cases and the risk of future public health threats arising from smallpox (variola virus), monkeypox virus, or other orthopoxviruses; update in Section VI the

definition of Covered Countermeasures to reflect amendments to the PREP Act and to refer explicitly to monkeypox; update section VIII to refer explicitly to monkeypox; extend in Section XII the effective time period of the declaration; and republish the declaration in its entirety, as amended.

Unless otherwise noted, all statutory citations below are to the U.S. Code.

#### Description of Amendments by Section

The Secretary is amending the title of the declaration to “Declaration, as Amended, for Public Readiness and Emergency Preparedness Act Coverage for Countermeasures against Smallpox, Monkeypox, and other Orthopoxviruses.”

#### Section I, Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

Before issuing a declaration under the PREP Act, the Secretary is required to determine that a disease or other health condition or threat to health constitutes a public health emergency or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency. This determination is separate and apart from a declaration issued by the Secretary under section 319 of the PHS Act that a disease or disorder presents a public health emergency or that a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists, or other declarations or determinations made under other authorities of the Secretary.

The Secretary is amending this determination to clarify that a risk of future public health threats is posed by smallpox (variola virus), monkeypox virus, or other orthopoxviruses, and to state that the 2022 outbreak of monkeypox cases in the United States presents a public health emergency for purposes of the PREP Act.

#### Section V, Covered Persons

The PREP Act's liability immunity applies to “Covered Persons” with respect to administration or use of a Covered Countermeasure. The term “Covered Persons” has a specific meaning and is

defined in the PREP Act to include manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees, and the United States.

A “qualified person” is one category of “covered person.” A qualified person means a licensed health professional or other individual who is authorized to prescribe, administer, or dispense Covered Countermeasures under the law of the state in which the countermeasure was prescribed, administered, or dispensed; or a person within a category of persons identified as qualified in the Secretary's declaration. Under this definition, the Secretary can describe in the declaration other qualified persons, who are Covered Persons.

Subject to certain limitations, a covered person is immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration or use of a Covered Countermeasure if a declaration under the PREP Act has been issued with respect to such countermeasure. To the extent that any State law that would otherwise prohibit a “qualified person” from prescribing, dispensing, or administering Covered Countermeasures, such law is preempted.<sup>1</sup> A State remains free to expand the universe of individuals authorized to administer Covered Countermeasures within its jurisdiction under State law.

The Secretary anticipates that there will be a need to increase the available pool of providers should a large-scale vaccination or therapeutic administration effort be required for the current monkeypox outbreak or future public health threats arising from smallpox (variola virus), monkeypox virus, or other orthopoxviruses. Variola virus, monkeypox virus, and other orthopoxviruses have the potential to inflict significant burden and strain on the U.S. healthcare system in their own right; and in conjunction with the ongoing COVID–19 pandemic, a spike in current monkeypox cases could overwhelm healthcare providers. The health care system capacity and the healthcare workforce are likely to become increasingly strained throughout the

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<sup>1</sup> See, “Preemption of State and Local Requirements Under a PREP Act Declaration,” Memorandum Opinion for the General Counsel Department of Health and Human Services, January 19, 2021, available at: <https://www.justice.gov/sites/default/files/opinions/attachments/2021/01/19/2021-01-19-prep-act-preemption.pdf>

nation. Allowing additional healthcare providers to administer smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics in accordance with applicable Federal Food and Drug Administration (FDA) licenses, approvals, or authorizations during a declared emergency allows states maximum flexibility in limiting potential impacts of illness. By this amendment to the declaration, the Secretary identifies additional categories of persons who are qualified persons covered by the PREP Act.

#### Section VI, Covered Countermeasures

The Secretary is amending Section VI to update the definition as amended by the CARES Act.

#### Section VIII, Category of Disease, Health Condition, or Threat

The Secretary is amending the category of disease, health condition, or threat for which he recommends the administration or use of the Covered Countermeasures to include explicitly disease and disease threat resulting from exposure to monkeypox virus.

#### Section XII, Effective Time Period

The Secretary must identify, for each Covered Countermeasure, the period or periods during which liability immunity is in effect, designated by dates, milestones, or other description of events, including factors specified in the PREP Act.

The Secretary is amending the declaration to extend the period for which liability immunity is in effect. The previous amended declaration was in effect through December 31, 2022. We have extended the effective time period to December 31, 2032.

### **Declaration, as Amended, for Public Readiness and Emergency Preparedness Act**

#### **Coverage for Countermeasures against Smallpox, Monkeypox, and other Orthopoxviruses**

This declaration amends and republishes the January 1, 2016 Amended Declaration Under the Public Readiness and Emergency Preparedness Act (“PREP Act”) for smallpox and other orthopoxvirus countermeasures. To the extent any term of the January 1, 2016 declaration is inconsistent with any provision of this republished declaration, the terms of this republished declaration are controlling.

## I. Determination of Public Health Emergency or Credible Risk of Future Public Health

### Emergency

42 U.S.C. 247d-6d(b)(1)

I have determined that there is a credible risk that smallpox (variola virus), monkeypox virus, or other orthopoxviruses and the resulting disease or conditions may in the future constitute a public health emergency and that the 2022 outbreak of monkeypox cases in the United States presents a public health emergency.

## II. Factors Considered

42 U.S.C. 247d-6d(b)(6)

I have considered the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the Covered Countermeasures.

## III. Recommended Activities

42 U.S.C. 247d-6d(b)(1)

I recommend, under the conditions stated in this declaration, the manufacture, testing, development, distribution, administration, or use of the Covered Countermeasures.

## IV. Liability Immunity

42 U.S.C. 247d-6d(a), 247d-6d(b)(1)

Liability immunity as prescribed in the PREP Act and conditions stated in this declaration is in effect for the Recommended Activities described in section III.

## V. Covered Persons

42 U.S.C. 247d-6d(i)(2),(3),(4),(6),(8)(A) and (B)

Covered Persons who are afforded liability immunity under this declaration are “manufacturers,” distributors, program planners, qualified persons, and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States.

In addition, I have determined that the following additional persons are qualified persons:

(a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in section VII below, to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasures, and their officials, agents, employees, contractors, and volunteers, following a declaration of an emergency, subject to the requirements of this paragraph:

The person so authorized must have documentation of completion of the Centers for Disease Control and Prevention (CDC)-provided or -recommended training for the countermeasure and any additional training required in the FDA license, approval, or authorization. In the absence of training requirements or recommendations from the CDC, other training(s) may be substituted if:

- (i) it is approved or accredited training from a national or state recognized accrediting body or association, the FDA, or equivalent organization for the administration route of the medical countermeasure,
- (ii) it includes hands-on instruction for the administration route as appropriate for the countermeasure, supervised by someone that administers within their normal scope of practice,
- (iii) it includes clinical evaluations of indications or contraindications of smallpox (variola virus), monkeypox virus, or other orthopoxvirus countermeasures, and
- (iv) it includes the recognition and treatment of emergency reactions to smallpox (variola virus), monkeypox virus, or other orthopoxvirus countermeasures;

If applicable, such additional training as may be required by the State, territory, locality, or Tribal area in which they are prescribing, dispensing, or administering smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics.

(b) Any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with section 564 of the Food, Drug, and Cosmetic (FD&C) Act.

(c) any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act.

(d) The following healthcare professionals and students in a healthcare profession training program following a declaration of an emergency as defined in section VII of this declaration, subject to the requirements of this paragraph:

1. To the extent not already licensed or authorized under state law, any dentist, advanced or intermediate emergency medical technician, licensed or certified professional midwife, nurse, advanced practice registered nurse, registered nurse, licensed practical nurse, optometrist, paramedic, pharmacist, pharmacy intern, pharmacy technician, physician, physician assistant, podiatrist, respiratory therapist, or veterinarian who is licensed or certified to practice under the law of any state who prescribes, dispenses, or administers smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics by the route of administration and to the population specified in the relevant FDA license, approval, or authorization, including intramuscular, intradermal, or subcutaneous injection, dermal/percutaneous scarification, intranasal or oral administration, that are Covered Countermeasures under section VI of this declaration in any jurisdiction where the PREP Act applies in association with a smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccination or therapeutics effort by a State, local, Tribal or territorial authority or by an institution in which the smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccine or therapeutic is administered;
2. Any dentist, advanced or intermediate emergency medical technician, licensed or certified professional midwife, nurse, advanced practice registered nurse, registered nurse, licensed practical nurse, optometrist, paramedic, pharmacist, pharmacy intern, physician, physician assistant, podiatrist, respiratory therapist, or veterinarian who has held an active license or certification under the law of any State within the last five years, which is inactive, expired or lapsed, who prescribes, dispenses, or administers smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics by the route of administration and to the population



specified in the relevant FDA license, approval or authorization, including intramuscular, intradermal, or subcutaneous injection, dermal/percutaneous scarification, intranasal or oral administration, that are Covered Countermeasures under section VI of this declaration in any jurisdiction where the PREP Act applies in association with a smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccination or therapeutics effort by a State, local, Tribal or territorial authority or by an institution in which the smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccine or therapeutic is administered, so long as the license or certification was active and in good standing prior to the date it went inactive, expired or lapsed and was not revoked by the licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General;

3. Any dental, advanced or intermediate emergency medical technician, medical, licensed or certified professional midwife, nursing, optometry, paramedic, pharmacy, pharmacy intern, physician assistant, podiatry, respiratory therapist, or veterinary student with appropriate training in administering vaccines or therapeutics as determined by their school or training program and supervision by a currently practicing healthcare professional, experienced in the route of administration and to the population specified in the relevant FDA license, approval, or authorization, who administers smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics by the route of administration and to the population specified in the relevant FDA license, approval, or authorization, including intramuscular, intradermal, or subcutaneous injection, dermal/percutaneous scarification, intranasal or oral administration that are Covered Countermeasures under section VI of this declaration in any jurisdiction where the PREP Act applies in association with a smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccination or therapeutics effort by a State, local,

Tribal or territorial authority or by an institution in which the smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccine or therapeutic is administered;

Subject to the following requirements:

- (i) The vaccine or therapeutic must be authorized, approved, or licensed by the FDA;
- (ii) Vaccination must be ordered and administered according to CDC's/ACIP's smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccine recommendation(s);
- (iii) The healthcare professionals and students must have documentation of completion of the CDC-provided or -recommended training for the countermeasure and any additional training required in the FDA licensing, approval, authorization. In the absence of training requirements or recommendations from the CDC, other training(s) may be substituted if:

- (1) it is approved or accredited training from a national or state recognized accrediting body or association, the FDA, or equivalent organization for the administration route of the medical countermeasure,
- (2) it includes hands-on instruction for the administration route as appropriate for the countermeasure, supervised by someone that administers within their normal scope of practice,
- (3) it includes clinical evaluations of indications or contraindications of smallpox (variola virus), monkeypox virus, or other orthopoxvirus countermeasures, and
- (4) it includes the recognition and treatment of emergency reactions to smallpox (variola virus), monkeypox virus, or other orthopoxvirus countermeasures;

If applicable, such additional training as may be required by the State, territory, locality, or Tribal area in which they are prescribing, dispensing, or administering smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics;

- (iv) The healthcare professionals and students must have documentation of an observation period by a currently practicing healthcare professional experienced in the appropriate route of intradermal, subcutaneous, or intramuscular injections, dermal/percutaneous scarification, intranasal or oral administration and for whom the appropriate route of intradermal,

subcutaneous, or intramuscular injections, dermal/percutaneous scarification, intranasal or oral administration is in their ordinary scope of practice, who confirms competency of the healthcare provider or student in preparation and administration of the smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics to be administered and, if applicable, such additional training as may be required by the State, territory, locality, or Tribal area in which they are prescribing, dispensing, or administering smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics;

(v) The healthcare professionals and students must have a current certificate in basic cardiopulmonary resuscitation;

(vi) The healthcare professionals and students must comply with recordkeeping and reporting requirements of the jurisdiction in which they administer vaccines or therapeutics, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine; and

(viii) The healthcare professionals and students comply with any applicable requirements (or conditions of use) as set forth in the CDC provider agreement and any other federal requirements that apply to the administration of smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics.

(e) Any healthcare professional or other individual who holds an active license or certification permitting the person to prescribe, dispense, or administer vaccines or therapeutics under the law of any State as of the effective date of this amendment, or healthcare professional as authorized under the sections V(d)(1) and (2) of this declaration, who, following a declared emergency as defined in section VII of this declaration, prescribes, dispenses, or administers smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics by the route of

administration and to the population specified in the relevant FDA license, approval, or authorization, including intramuscular, intradermal, or subcutaneous injection, dermal/percutaneous scarification, intranasal or oral administration that are Covered Countermeasures under section VI of this declaration in any jurisdiction where the PREP Act applies, other than the State in which the license or certification is held, in association with a smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccination or therapeutics effort by a federal, State, local Tribal or territorial authority or by an institution in the State in which the smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccine or therapeutic is administered, so long as the license or certification of the healthcare professional has not been suspended or restricted by any licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General, subject to:

(i) documentation of completion of the appropriate training; CDC provided or recommended training for the countermeasure and any additional training required in the FDA license, approval, or authorization. In the absence of training requirements or recommendations from the CDC, other training(s) may be substituted if:

- (1) it is approved or accredited training from a national or state recognized accrediting body or association, the FDA, or equivalent organization for the administration route of the medical countermeasure,
- (2) it includes hands-on instruction for the administration route as appropriate for the countermeasure, supervised by someone that administers within their normal scope of practice,
- (3) it includes clinical evaluations of indications or contraindications of smallpox (variola virus), monkeypox virus, or other orthopoxvirus countermeasures, and
- (4) it includes the recognition and treatment of emergency reactions to smallpox (variola virus), monkeypox virus, or other orthopoxvirus countermeasures;

If applicable, such additional training as may be required by the State, territory, locality, or Tribal area in which they are prescribing, dispensing, or administering smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics;

and

(ii) for healthcare providers who are not currently practicing, documentation of an observation period by a currently practicing healthcare in experienced in the appropriate route of intradermal, subcutaneous, or intramuscular injections, dermal/percutaneous scarification, intranasal or oral administration , and for whom the appropriate route of intradermal, subcutaneous, or intramuscular injections, dermal/percutaneous scarification, intranasal or oral administration is in their ordinary scope of practice, who confirms competency of the healthcare provider in preparation and administration of the smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics to be administered.

(f) Any member of a uniformed service (including members of the National Guard in a Title 32 duty status) (hereafter in this paragraph “service member”) or Federal government employee, contractor, or volunteer who prescribes, administers, delivers, distributes, or dispenses smallpox (variola virus), monkeypox virus, or other orthopoxvirus Covered Countermeasures. Such Federal government service members, employees, contractors, or volunteers are qualified persons if the following requirements are met:

(i) The executive department or agency by or for which the Federal service member, employee, contractor, or volunteer is employed, contracts, or volunteers has authorized or could authorize that service member, employee, contractor, or volunteer to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure as any part of the duties or responsibilities of that service member, employee, contractor, or volunteer, even if those authorized duties or responsibilities ordinarily would not extend to members of the public or otherwise would be more limited in scope than the activities such service member, employees, contractors, or volunteers are authorized to carry out under this declaration;

(ii) The Federal service member or Federal government, employee, contractor, or volunteer must have documentation of completion of the CDC provided or recommended training for the countermeasure and any additional training required in the FDA license, approval, or authorization. In the absence of training requirements or recommendations from the CDC, other training(s) may be substituted if:

- (1) it is approved or accredited training from a national or state recognized accrediting body or association, the FDA, or equivalent organization for the administration route of the medical countermeasure,
- (2) it includes hands-on instruction for the administration route as appropriate for the countermeasure, supervised by someone that administers within their normal scope of practice,
- (3) it includes clinical evaluations of indications or contraindications of smallpox (variola virus), monkeypox virus, or other orthopoxvirus countermeasures, and
- (4) it includes the recognition and treatment of emergency reactions to smallpox (variola virus), monkeypox virus, or other orthopoxvirus countermeasures;

If applicable, such additional training as may be required by the State, territory, locality, or Tribal area in which they are prescribing, dispensing, or administering smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics.

## VI. Covered Countermeasures

42 U.S.C. 247d-6b(c)(1)(B), 42 U.S.C. 247d-6d(i)(1) and (7)

Covered Countermeasures are any vaccine, including all components and constituent materials of these vaccines, and all devices and their constituent components used in the administration of these vaccines; any antiviral; any other drug; any biologic; or any diagnostic or other device to identify, or any respiratory protective device to prevent or treat smallpox (variola virus), monkeypox virus, or other orthopoxvirus or adverse events from such countermeasures.

Covered Countermeasures must be “qualified pandemic or epidemic products,” or “security countermeasures,” or drugs, biological products, or devices authorized for investigational or

emergency use, or a respiratory protective device as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

## VII. Limitations on Distribution

### 42 U.S.C. 247d-6d(a)(5) and (b)(2)(E)

I have determined that liability immunity is afforded to Covered Persons only for Recommended Activities involving Covered Countermeasures that are related to:

(a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements, or activities directly conducted by the federal government; or

(b) Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasures following a declaration of an emergency.

i. The Authority Having Jurisdiction means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (e.g., city, county, tribal, state, or federal boundary lines) or functional (e.g., law enforcement, public health) range or sphere of authority.

ii. A declaration of emergency means any declaration by any authorized local, regional, state, or federal official of an emergency specific to events that indicate an immediate need to administer and use the Covered Countermeasures, with the exception of a federal declaration in support of an Emergency Use Authorization under section 564 of the FD&C Act unless such declaration specifies otherwise.

I have also determined that for governmental program planners only, liability immunity is afforded only to the extent such program planners obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from State, local, or private stockpiles.

## VIII. Category of Disease, Health Condition, or Threat

42 U.S.C. 247d-6d(b)(2)(A)

The category of disease, health condition, or threat for which I recommend the administration or use of the Covered Countermeasures is smallpox resulting from exposure to variola virus, monkeypox resulting from exposure to monkeypox virus, or other infectious disease resulting from exposure to other orthopoxviruses, and the threat of disease resulting from exposure to any of these viruses.

## IX. Administration of Covered Countermeasures

42 U.S.C. 247d-6d(a)(2)(B)

Administration of the Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for purpose of distributing and dispensing countermeasures.

## X. Population

42 U.S.C. 247d-6d(a)(4), 247d-6d(b)(2)(C)

The populations of individuals include any individual who uses or is administered the Covered Countermeasures in accordance with this declaration.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered to this population or the program planner or qualified person reasonably could have believed the recipient was in this population.

## XI. Geographic Area

42 U.S.C. 247d-6d(a)(4), 247d-6d(b)(2)(D)



Liability immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered in these geographic areas; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered in these geographic areas, or the program planner or qualified person reasonably could have believed the recipient was in these geographic areas.

## XII. Effective Time Period

### 42 U.S.C. 247d-6d(b)(2)(B)

Liability immunity for Covered Countermeasures obtained through means of distribution other than in accordance with the public health and medical response of the Authority Having Jurisdiction extends through December 31, 2032.

Liability immunity for Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction begins with a declaration and lasts through (1) the final day the emergency declaration is in effect or (2) December 31, 2032, whichever occurs first.

Liability immunity for Covered Countermeasures administered and used by additional qualified persons in sections V(d) and V(e) begins with a declaration and lasts through (1) the final day the emergency declaration is in effect or (2) December 31, 2032, whichever occurs first.

Covered Countermeasures obtained for the Strategic National Stockpile (SNS) during the effective period of this declaration for Covered Countermeasures are covered through the date of administration or use pursuant to a distribution or release from the SNS.

## XIII. Additional Time Period of Coverage

### 42 U.S.C. 247d-6d(b)(3)(A), (B) and (C)

I have determined that an additional twelve (12) months of liability protection is reasonable to allow for the manufacturer(s) to arrange for disposition of the Covered Countermeasure, including return of the Covered Countermeasures to the manufacturer, and for Covered Persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasures.

#### XIV. Countermeasures Injury Compensation Program

42 U.S.C. 247d-6e

The PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a serious physical covered injury as the direct result of the administration or use of the Covered Countermeasures and/or benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures. The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical and scientific evidence in order for the individual to be considered for compensation. The CICP is administered by the Health Resources and Services Administration, within the Department of Health and Human Services. Information about the CICP is available at 855-266-2427 (toll-free) or <http://www.hrsa.gov/cicp/>.

#### XV. Amendments

42 U.S.C. 247d-6d(b)(4)

The October 10, 2008 declaration under the PREP Act for smallpox countermeasures was first published on October 17, 2008 and amended and republished on January 1, 2016. This is the second amendment to and republication of the declaration.

Any further amendments to this declaration will be published in the Federal Register.

(Authority: 42 U.S.C. 247d-6d)

**Xavier Becerra,**

*Secretary.*

